

CLAIMS

1. A solid composition comprising a biologically active agent dissolved in a carrier system, wherein the carrier system includes an unsaturated fatty acid alcohol in combination with an alkylene glycol selected from propylene glycol, butylene glycol, dipropylene glycol and/or dibutylene glycol as a solvent for the active agent and a stiffening agent for imparting a solid consistency to the composition, said alkylene glycol being present in an amount that gives mutual dissolution with said unsaturated fatty acid alcohol as well as dissolution of said active agent.

2. A composition as claimed in claim 1, wherein the amount of said alkylene glycol is more than 12 % by weight, based on the total weight of the carrier system.

3. A composition as claimed in claim 2, wherein the amount of said alkylene glycol is at least 15 % by weight.

4. A composition as claimed in ~~any one of the preceding claims~~, wherein said unsaturated fatty acid alcohol is an unsaturated C<sub>16</sub>-C<sub>20</sub>-fatty acid alcohol, preferably an unsaturated C<sub>18</sub>-fatty acid alcohol.

5. A composition as claimed in claim 4, wherein said unsaturated C<sub>18</sub>-fatty acid alcohol is selected from oleyl alcohol, ricinolyl alcohol, linolyl alcohol and/or linolenyl alcohol, preferably oleyl alcohol.

6. A composition as claimed in ~~any one of the preceding claims~~, wherein the stiffening agent is a viscosity enhancing agent capable of imparting a soft and erodible consistency to the composition.

7. A composition as claimed in ~~any one of the preceding claims~~, wherein the biologically active agent is a lipophilic compound, preferably a lipophilic drug.

8. A composition as claimed in claim 7, wherein the biologically active compound is selected from steroids, including corticosteroids, sex hormones, including andro-

gens and estrogens and derivatives thereof, vitamins, including vitamins A, D2, D3, E, K and derivatives thereof, biologically active lipids, fatty acids, antibiotics and antimicrobials, including antivirals, antibacterials, 5 antiprotozoals and antifungals, and local anesthetics, preferably of the amide type.

9. A composition as claimed in claim 8, wherein the biologically active compound is selected from fluocinonide, omega-3-fatty acid and azelaic acid and salts and 10 eters thereof.

10. A composition as claimed in claim 8, wherein the biologically active compound is clobetasol or a salt or an ether thereof, preferably clobetasol propionate.

11. A composition as claimed in any one of the preceding claims, wherein the alkylene glycol is propylene glycol.

12. A composition as claimed in any one of the preceding claims, wherein the solvent additionally comprises a C<sub>1</sub>-C<sub>6</sub>-alkanol ester of a fatty acid and/or a C<sub>1</sub>-C<sub>6</sub>-20 alkanol ester of sorbic acid.

13. A composition as claimed in claim 12, wherein said additional solvent comprises propyl (incl. isopropyl) myristate, palmitate, oleate, stearate and/or laurate, and/or the propyl (incl. isopropyl) ester of sorbic acid.

14. A composition as claimed in claim 13, wherein said additional solvent is isopropylpalmitate.

15. A composition as claimed in any one of the preceding claims, wherein the viscosity enhancing agent is a 30 waxy substance.

16. A composition as claimed in claim 15, wherein the waxy substance comprises a natural and/or synthetic wax, preferably a monoester of a long-chained carboxylic acid with a long-chained alcohol; a fat, preferably a triglyceride of a C<sub>18</sub>-C<sub>36</sub> fatty acid; a glycol ester of a C<sub>18</sub>-C<sub>36</sub> fatty acid; or a mixture of two or more such compounds.

17. A composition as claimed in claim 16, wherein the waxy substance comprises a combination of a natural or synthetic wax and a triglyceride and/or a glycol ester.

18. A composition as claimed in any one of the preceding claims, wherein the carrier system also comprises an oil capable of plasticizing the viscosity enhancing agent and reducing the viscosity of the carrier system.

19. A composition as claimed in claim 18, wherein the plasticizing oil is selected from low molecular weight aliphatic acids and alcohols, preferably having branched chains, and preferably is fluid lanoline.

20. A composition as claimed in any one of the preceding claims, wherein the amount of solvent is within the range of 20-85 % by weight, the amount of viscosity enhancing agent is within the range of 15-80 % by weight and the amount of plasticizing oil is within the range of 0-30 % by weight, based on the total weight of the carrier system.

21. A composition as claimed in claim 20, wherein the amount of solvent is within the range of 25-75, preferably 40-60, % by weight, the amount of viscosity enhancing agent is within the range of 15-55, preferably 25-50, % by weight and the amount of plasticizing oil is within the range of 0-30, preferably 2-20, % by weight.

22. A composition as claimed in any one of the preceding claims, wherein the amount of said alkylene glycol is within the range of 12-23, preferably 15-23, % by weight, more preferably 12-20, especially 15-20, % by weight.

23. A composition as claimed in any one of claims 12-22, wherein the weight ratio of unsaturated fatty acid alcohol : additional solvent is within the range of 1:2 to 5:1, preferably 1:2 to 3:1, especially 1:2 to 2:1.

24. A composition as claimed in any one of the preceding claims, wherein the biologically active agent is

present in a concentration of up to the solubility limit thereof in the carrier system.

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25. A composition as claimed in ~~any one of the preceding claims~~, wherein the concentration of the biologically active agent is 0,01-10, preferably 0,02-5, % by weight, based on the weight of the carrier system.

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*a*

5 26. A composition as claimed in ~~any of the preceding claims~~, wherein said composition is a stick composition.

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*a*

10 27. A composition as claimed in ~~any one of the preceding claims~~ for use as a medicament, said biologically active agent being a therapeutically or prophylactically active agent.

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15 28. A composition as claimed in claim 27, for topical application to the skin of a mammal, especially man, wherein the composition has a viscosity that is adapted for such application.

20 29. A composition as claimed in any of the preceding claims, wherein the biologically active compound is betamethasone, or a salt or ester thereof, preferably betamethasone-17-valerate or betamethasone dipropionate.

30 30. Use of a composition as claimed in any of the preceding claims for the preparation of a medicament for therapeutic or prophylactic treatment of a dermatological condition.

25 31. A use as claimed in claim 30, wherein the composition is as claimed in any one of claims 2-29.

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30 32. A process for the preparation of a biologically active composition as claimed in ~~any of claims 1-29~~, comprising dissolving the biologically active agent in said solvent therefor, combining the resulting solution with a viscosity enhancing agent so as to impart a solid consistency to said solution and shaping the resulting composition into a desired form.

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